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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,546	01/18/2002	Gregory A. Demopulos	OMER118473	6615

26389 7590 07/01/2005

CHRISTENSEN, O'CONNOR, JOHNSON, KINDNESS, PLLC
1420 FIFTH AVENUE
SUITE 2800
SEATTLE, WA 98101-2347

EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,546	DEMOPULOS ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-60 and 73-81* is/are pending in the application.

4a) Of the above claim(s) *40-43,55-59,61-72 and 77-80* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38,39,44-54,59,60,73-76 and 81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 10/29/02; 4/24/02; 3/25/03; 4/26/05; 1/8/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Information Disclosure Statements dated 10/29/02, 11/24/02, 3/25/03, 1/08/05 and 4/26/05.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 38-60 and 73-81, drawn to a method of inhibiting cartilage damage comprising the delivery of a composition locally to the joint, classified in class 424, subclass 422.

   II. Claims 61-72, drawn to a method of inhibiting cartilage damage comprising the delivery of a composition locally to a joint during varying stages of an operation, classified in class 424, subclass 423.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions The inventive method of group II requires an arthroscopic surgical procedure while the method of group I requires no such procedure. The invention of group I can be applied at any time while the invention of group II requires further procedures including arthroscopic surgery.

3. This application contains claims directed to the following patentably distinct species of the claimed invention:

   a. The delivery vehicle: applicant must choose between

i. Microparticles, microspheres, nanoparticles,

ii. Proteins,

iii. Liposomes

iv. Carbohydrate

v. Synthetic organic compounds

vi. Inorganic compounds

b. The delivery mechanism: applicant must choose between

vii. Injection

viii. Infusion

ix. Regulated delivery pump

c. The anabolic chondropretective agents: applicant must choose

x. Interleukin

xi. Transforming growth factor

xii. Fibroblast growth factor

d. The inhibitor of catabolic activity: applicant must choose between

xiii. IL-1 receptor

xiv. TNF-alpha receptor

xv. Cyclooxygenase-2

xvi. MAP kinase receptor

xvii. Nitric oxide synthase receptor

xviii. Nuclear factor kB inhibitor

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 38 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant chose to elect group I claims 38-60 and 73-81. Applicant has elected carbohydrates as the delivery vehicle, injection as the delivery mechanism, fibroblast growth factors as the anabolic chondroprotective agents, and M.A.P. kinase inhibitors as the inhibitors of cartilage catabolism. These selections are drawn to claims 38, 39, 44-54, 59, 60, 73-76 and 81. Currently claims 38, 44-54, 59, 60, 73-75 and 81 are held as generic. The prosecution of claims 38,39, 44-54, 59, 60, 73-76 and 81 is as follows:

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 38,39,44-54,59,60,73-76 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Collins et al (USPN 6,096,728 hereafter '728) and Hunziker (USPN 5,206,023 hereafter '023). The claims are drawn to method of inhibiting

cartilage degradation in a joint comprising delivering to the joint a composition comprising two chondroprotective agents.

4. The '728 patent teaches a method and formulation for the treatment of inflammatory diseases (abstract). The method requires the administration of a formulation comprising Interleukin 1 inhibitors in combination with various therapeutic compounds and carriers (col. 25, lin. 52-65). The additional compounds include MAP kinase inhibitors such as SB203580 (col. 32, lin. 17), and anti-inflammatory agents when the composition is used for the treatment of chronic osteoarthritis, psoriatic arthritis and/or rheumatoid arthritis (col. 34, lin. 6-24). The compounds can be injected intra-articulately (col. 35, lin. 13-col. 36, lin. 60) before, during or after a trauma or surgical procedure (*Ibid.*). The reference is however silent to the inclusion of fibroblast growth factors.

5. The '023 patent teaches methods for the treatment and repair of defects of lesions in cartilage (abstract). The method includes the delivery via injection a composition comprising various therapeutic compounds such as fibroblast growth factors (col. 4, lin. 49-64). The growth factors are combined with other components in methods to treat defects in knee cartilage (examples).

6. Since both '728 and '023 disclose compositions for the treatment of cartilage damage, it would be well within the level of skill in the art to combine them in order to provide an improved cartilage treatment composition. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically

from their having been individually taught in the prior art. *See* In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)

7. With these things in mind it would have been obvious to combine the compounds of '023 and '728 in order to produce an improved method of treatment. The method of '728 requires a mixture of ingredients including anti-inflammatory agents, and inhibitors of catabolic action. It would be within the level of skill in the art to combine these compounds with those of '023 since the compounds of both references are useful in the treatment of damaged cartilage. It would have been obvious to make this combination with an expected result of an improved treatment method for damaged cartilage.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1618

MP Young

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600